III. Provisions of This Interim Final Rule With Comment Period

A. Changes Relating to the BBRA 1999 Public Comments

Except for the changes discussed in the preamble, we are adopting the BBRA 1999 provisions implemented in the April 7, 2000 final rule with comment period and the August 3, 2000 interim final rule with comment period, described in section II of this preamble, as final without modification. We are making the following changes to the regulation text as a result of the public comments received:

We are revising § 419.41(c)(4)(i) to provide that, effective January 1, 2001, when multiple APCs for a single drug or biological are furnished to a beneficiary on the same day, the inpatient hospital deductible limitation on coinsurance will be applied to the aggregate coinsurance for the drug or biological. The section is further revised to provide that, effective July 1, 2001, the coinsurance amount for the procedure or service that resulted in the administration of the drug or biological will be aggregated with the coinsurance for the drug or biological in applying the limit.

We are revising § 419.70(f)(2)(ii) to remove the phrase "without applying the cost reductions under section 1861(v)(1)(S) of the Act". We recognize that the phase may have inadvertently caused confusion to the extent it is redundant, as pointed out by a commenter.

B. Annual Updates to Components of the Hospital Outpatient Prospective Payment System

In this interim final rule with comment period, for calendar year 2001, we are updating the wage index and the conversion factor adjustment for covered hospital outpatient services furnished beginning January 1, 2001. We also are updating the existing APC groups to reflect new codes that have been assigned. In accordance with section 1833(t)(9)(A) of the Act and section 201(h)(2) of the BBRA 1999, we will undertake a complete system update in 2001 for hospital outpatient prospective payments. That update will take effect on January 1, 2002. We will consult with an expert outside advisory panel composed of appropriate representatives of providers. This panel will review and advise us concerning the clinical integrity of the APC groups and relative weights. The panel will be allowed to use data other than those we have collected or developed during our review of the APC groups and relative weights.

1. APC Groups

We are updating the existing APC groups effective January 1, 2001 to reflect the addition of new CPT and alpha-numeric codes, the deletion of invalid codes, changes to the list of procedures we pay for only in an inpatient setting (the "inpatient list"), the creation of a new status indicator, newly covered procedures, reconfigurations due to the inclusion of device costs, and revisions to correct errors and provide consistency in the placement of codes.

a. New codes

There are 936 new codes, 645 of which are "C" codes. "New" in this context means new since the April 7, 2000 final rule with comment period was published. Many of the "C" codes were published in program memoranda over the intervening months. New codes are shown in Addendum B with an asterisk in the column preceding the code.

b. Deleted codes

With the exception of "C" codes, codes deleted effective January 1 of each year are given a 3-month grace period in which they will still be recognized. "C" codes are temporary codes used exclusively to bill pass-through items and new technology services and items paid under the

hospital prospective payment system. We will retire these codes prospectively at the start of a new calendar quarter based on specific service dates and are not extending the same 3-month grace period to them. We will drop all non "C" codes from APCs effective April l. Deleted codes are shown in Addendum B. They are followed by the letter D. The AMA's CPT books also list deleted codes.

c. Revisions to correct errors or inconsistencies

We are revising the APCs in order to correct errors and to provide greater consistency in the placement of codes. For example, we had assigned various types of cardiovascular diagnostic tests to four APCs, with rates based on data that, on subsequent review, appeared limited. We are recategorizing these APCs. This recategorization results in three APCs with greater clinical coherence.

Medicare covers influenza, pneumococcal, and hepatitis B immunizations routinely, with no copayment or deductible due for flu and pneumonia vaccines or their administration. Other vaccines may be covered in certain circumstances, but are, in fact, given so infrequently that our cost data are limited. We are rearranging the preventive vaccines and assigning the less frequently furnished vaccines based on their reported costs, but

within a smaller range. We expect very few immunizations other than influenza and pneumonia to be billed, but if they are billed, we will update our data.

We also are changing the APCs to which bone density studies are assigned. The codes used in 1996 captured both central and peripheral bone density studies. Coding changes since that time have separated the two types of studies, but this distinction was not reflected in the 1996 data. In order to better reflect these differences, we are separating the various codes and assigning central dual energy x-ray absorptiometry (DEXA) bone density studies to a new technology APC.

We did not include the codes for transfusion laboratory services (for example, typing and crossmatching) in APCs in the April 7, 2000 final rule with comment period. We are now creating three APCs to capture these codes, and an additional APC to capture fertility procedures.

d. Device-related codes

As described in the April 7, 2000 final rule with comment period, revenue centers 274, 275, and 278 were not included for purposes of calculating the APC rates because prior to the BBRA 1999, we anticipated paying for durable

medical equipment and prosthetics (including implantable devices) outside of the outpatient prospective payment system and it was unfeasible to revise our database to reflect the revenue centers in time to publish a final rule and implement the prospective payment system by July 1, 2000. To reflect the inclusion of implantable devices as required under the BBRA 1999, we have recalculated APC rates with these revenue centers included. As a result, the median cost for certain procedures such as inserting pacemakers, replacing leads, and providing neurostimulators increased significantly.

In order to recognize these cost increases, which are attributable to the devices, and to aid in the assignment of devices to APCs at the end of the pass-through period, we are reconfiguring certain APCs. That is, we are creating APC groups for the insertion of pacemakers, the replacement of pacemaker electrodes, the implantation of a pacemaker and electrodes, and the removal of a pacemaker. These changes reflect our basic criteria that procedures within an APC group be clinically similar and comparable in terms of resources, with the highest cost item or service within a group being no more than 2 times greater than the lowest cost item or service within the same group.

e. Inpatient codes moved to the outpatient setting

In response to numerous requests, we reviewed the composition of the inpatient list. While we continue to believe that we have the majority of the codes assigned properly, for the reasons discussed in section III.B.2. we are persuaded to move a number of codes to the outpatient setting. We are able to place most codes into closely related APCs.

f. "Two-times" rule

The BBRA 1999 required us to ensure that no APC contains codes such that the highest median cost in the APC exceed twice the lowest median cost. We undertook an analysis of APCs in relation to this requirement as part of the 2001 update. (Note that the law provides for exceptions based on low volume and other reasons. We consider a code that captures fewer than 2 percent of the services within an APC to be low volume, and we disregard codes for unlisted services or procedures, since we do not know what service or procedure was billed.) For example, moving a radical mastectomy code from the inpatient list to a breast procedure APC caused the group to fail the two-times test. In another instance, as described above, we packaged costs associated with implantable devices into the

relevant procedure codes. This change would also cause device-related APCs to fail the two-times test. For these situations and others that failed the two-times test, we are reconfiguring the APCs appropriately.

g. Inpatient codes moved to outpatient and affected by device

Seven codes related to vascular and neurological procedures were moved from the inpatient list into APCs, that were then split according to device use, in response to comments.

h. Newly covered codes

The updated APCs reflect recent HCFA decisions to provide Medicare coverage for an electrical bioimpedance procedure and three magnetic resonance angiography services. The codes for these newly covered services are M0302 and 71555, 73725, and 74185, respectively.

i. Pass-through requests for drugs

Since publication of the April 7, 2000 final rule with comment period, we have received additional requests for pass-through status for a number of drugs. The codes for the additional eligible pass-through drugs are shown in Addendum B.

The following table contains a listing of the changes in the APC groups discussed above.

Summary of Changes to APCs

NEW CODES	CHANGES TO APC PLACEMENT OF EXISTING CODES						
	Revisions or corrections of errors	**Device-related codes**	**Inpatient moved to outpatient**	**"Two-times" rule**	**Inpatient codes moved to outpatient and affected by device**	**Newly covered codes**	**Pass-through requests for drugs**
936 codes added, 645 of which are "C" codes	111 codes changed	87 codes changed	56 codes changed (12 as of 8/1/2000)	25 codes changed	7 codes changed	4 codes changed	4 codes changed
Denoted by asterisk in Addendum B	APCs 0004, 0087, 0099, 0100, 0102, 0123, 0282, 0340, 0342, 0346, 0347, 0348, 0349, 0354, 0356, 0602, 0761, 0970, 0971, 0974, 0976, 1044, 1401, 1402, 1403, 1404, 1405, 1406, 1407, and 1409	APCs 0082, 0083, 0089, 0091, 0093, 0103, 0104, 0105, 0106, 0107, 0108, 0109, 0115, 0119, 0124, 0185, 0224, 0225, 0226, 0227, 0228, 0229, 0256, and 1002	APCs 0005, 0020, 0021, 0029, 0046, 0050, 0081, 0114, 0115, 0120, 0121, 0162, 0165, 0194, 0195, 0198, 0216, 0254, 0256, 0263, 0264, 0279, 0280, 0970, 0974, and 0981.	APCs 0028 and 0029	HCPCS 37620 35011 36834 61880 61888 33284 63741	HCPCS 71555 73725 74185 M0302	HCPCS J1650 J2770 J1810 J7315

Addenda A and B reflect changes to the APC groups, effective January 1, 2001. Addendum C, entitled "Hospital Outpatient Department (HOPD) Payment for Procedures by APC, Calendar Year 2001," is not published in this interim final rule with comment period, but will be posted on our website at http://www.hcfa.gov/medlearn/refopps.htm. Addendum C will display data similar to those contained in Addenda A and B, but sorted by APCs with each procedure code listed that is assigned to the APC.

2. Inpatient Procedures List Update

In the preamble to the April 7, 2000 final rule with comment period, we indicated that, as part of our annual update process, we would update the procedures on the inpatient list. The first annual revision of this list is effective on January 1, 2001. We are removing 44 procedures from the list and placing them in APCs. (Several procedures that were inadvertently left on the inpatient list in the April 7, 2000 final rule with comment period were removed from the list and placed in APCs in August 2000.) The revised list is included in Addendum E.

We have attempted to limit the inpatient only list to those procedures that, in current medical practice as

understood by our clinical staff, require inpatient care, such as those that are highly invasive, result in major blood loss or temporary deficits of organ systems (such as neurological impairment or respiratory insufficiency), or otherwise require intensive or extensive postoperative care. Insofar as advances in medical practice mitigate concerns about these procedures being performed on an outpatient basis, we will be prepared to remove them from the inpatient list and provide for payment under the hospital outpatient prospective payment system.

Since the April 7, 2000 final rule with comment period was published, we have received requests to move a number of procedures from the inpatient list because, based on medical evidence, the procedures can be performed safely in a hospital outpatient setting. These included breast and other cancer procedures, repairs of facial trauma, many orthopedic procedures, several vascular procedures, and some genito-urinary procedures.

Among the procedures we are removing from the inpatient list and placing in APCs as a result of these requests are excision of chest wall tumors, several orthopedic repairs, vascular procedures, and ureteral

endoscopies. We are moving overnight pulse oximetry from the inpatient list to packaged status. We also are moving several comparable procedures, for example, related ureteral endoscopies.

At this time, we are not removing from the inpatient list various spinal procedures, including osteotomies and laminectomies. We also are not removing several open abdominal and retroperitoneal procedures from the inpatient list because many of these procedures involve prolonged invasion of the thoractic cavity, the peritoneum, or the retroperitoneal space. Patients undergoing these procedures typically require prolonged postoperative monitoring. Moreover, the information provided to us by requesters did not provide convincing evidence that these procedures are currently being performed or can be safely performed in an outpatient setting. However, we are aware that, with advances in technology and surgical techniques, many of these procedures may eventually be performed safely in a hospital outpatient setting. We will continue to review all the procedures on the inpatient list and will consider additional requests to move specific procedures to the outpatient setting. We ask that these requests contain

detailed rationale along with medical evidence that the procedure may be performed safely in an outpatient setting.

We note that, in some instances, requests for removing a particular procedure from the inpatient list may have resulted from a misunderstanding about appropriate coding. Less invasive versions of the procedure on the inpatient list may be in an APC. The presence of certain thoracoscopies on the inpatient list, for example, does not mean that no thoracoscopy will be paid under the outpatient prospective payment system.

We also were asked to move several procedures from APCs to the inpatient list. Because of the rapid advance in technology and surgical techniques mentioned above, we believe that if procedures have been assigned APCs, we should not reverse that status unless it becomes obvious that we have made an error. Thus, we are moving to the inpatient setting only one of the codes for which we received a request (open treatment of a knee dislocation, which requires more than outpatient postoperative monitoring), and two other codes (for nephrectomy with total ureterectomy and for escharotomy) that had been assigned APCs in error.

Beginning in April 2001, we will, if warranted, revise the inpatient list at least quarterly to better reflect changes in medical practice that permit procedures that were previously performed only in an inpatient setting to be safely and effectively performed in an outpatient setting. In the April 7, 2000 final rule with comment period, we discussed our intent to revise the list as part of the annual update of APCs and asked that interested parties advise us of procedures that can be performed in an outpatient setting. Since we will be making quarterly updates to the outpatient prospective payment system for other purposes, we will also change the inpatient list quarterly, if warranted. Generally, because of systems limitations, 3 months or more are required after a decision is made before we can implement a change.

The inpatient list was not a result of a provision of the BBRA 1999; it was included in the September 1998 proposed rule and we responded to comments and made the provision final in the April 7, 2000 final rule with comment. Accordingly, we did not request comments on our policy on the establishment of the inpatient list at that time. Nonetheless, we received a number of comments

concerning the existence of this list, the provisions for updating it, and its implications for other Medicare payment systems. We will consider these comments and expect to discuss the matter further in the proposed rule updating the hospital outpatient prospective payment system for 2002, which we will publish in the spring of 2001.

3. Wage Index Adjustment

Under section 1833(t)(2)(D) of the Act, we are required to determine a wage adjustment factor to adjust, in a budget neutral manner, the portion of the payment rate and the coinsurance amount that is attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions under the hospital outpatient prospective payment system.

In the April 7, 2000 final rule with comment period, we specified, in regulations at § 419.43(c), that each year we use the hospital inpatient prospective payment system wage index established in accordance with 42 CFR Part 412 to make a wage adjustment for relative differences in labor and labor-related costs across geographic areas under the hospital outpatient prospective payment system. We note that, by statute, we implement the annual update of the

hospital inpatient prospective payment system on a fiscal year basis. However, we update the hospital outpatient prospective payment system on a calendar year basis. Therefore, the hospital inpatient prospective payment system wage index values established for urban and rural areas and for reclassified hospitals published in the **Federal Register** on August 1, 2000 (65 FR 47149 through 47157) are being applied for wage adjustments under the hospital outpatient prospective payment system, effective January 1, 2001. The fiscal year 2001 hospital inpatient wage index reflects the effects of hospitals redesignated under section 1886(d)(8)(B) of the Act and hospital reclassifications under section 1886(d)(10) of the Act. After publication of the hospital inpatient wage index values for fiscal year 2001 on August 1, 2000, we discovered several errors in the values for several geographic areas. The correct wage index values for all areas are republished in Addenda F, G, and H of this interim final rule with comment period.

In this interim final rule with comment period, we are establishing the methodology that we will use in making adjustments for area wage differences for services

furnished in the Virgin Islands. We note that a hospital inpatient prospective payment system wage index value is not calculated for the Virgin Islands because there are no hospitals located in that area that are paid under the inpatient hospital prospective payment system. Because the wage index that we adopted in our April 7, 2000 final rule with comment period does not include a value for adjusting wage differences for the Virgin Islands, we will use the wage index for the Virgin Islands as calculated for the skilled nursing facilities prospective payment system to make this adjustment. The skilled nursing facilities prospective payment system uses the inpatient hospital wage index data to adjust its prospective payment rates for the same fiscal year (that is effective October 1, 2000) as covered by the hospital inpatient prospective payment system wage index values. As stated in the July 31, 2000 skilled nursing facilities prospective payment system final rule (65 FR 46770), "The computation of the wage index...incorporate[s] the latest data and methodology used to construct the hospital wage index. For these reasons, the wage index adjustment that we will apply to the Virgin

Islands for services furnished on or after January 1, 2001 is 0.6306.

Although the wage index for skilled nursing facilities is based on a fiscal year beginning October 1, we will apply the wage index factor for the Virgin Islands that goes into effect on October 1 of each year to the hospital outpatient prospective payment system services furnished during the following calendar year. This is consistent with how we apply the hospital inpatient prospective payment system wage index values to the hospital outpatient prospective payment system services.

Consistent with the methodology applicable for services furnished in 2000 (on or after August 1, 2000), in making adjustments for area wage differences for services furnished in 2001, we will recognize 60 percent of the hospital's costs as labor-related costs that are standardized for geographic wage differences.

4. Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires us to update annually the conversion factor used to determine APC payment rates. Section 1833(t)(3)(C)(iii) of the Act provides that the update be equal to the hospital inpatient

market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act, reduced by one percentage point for the years 2000, 2001, and 2002. Thus, the update to the outpatient hospital prospective payment system conversion factor for 2001 is 2.4 percent (3.4 percent minus 1 percent).

In accordance with section 1833(t)(9)(B) of the Act, the conversion factor for 2001 also has been adjusted to ensure that the revisions we made to update the wage index

are made on a budget-neutral basis. A budget neutrality factor of .9989 was calculated for wage index changes by comparing total payments from our simulation model using the wage index values that will be effective January 1, 2001.

The market basket increase of 2.4 percent for 2001 and the required budget neutrality adjustment calculated to be .9989 result in a conversion factor for 2001 of $49.596.